newdeal
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PARC D'ACTIVITÉS GARIGLIANO
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AUG 3 0 2001

K011716

SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

NewDeal SA
Parc d'Activités Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE

Tél. : (33) 4 74 78 15 15
Fax : (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854
estrin@yourFDAconsultant.com
Tel. : (301) 279 -2899
Fax : (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: May 31, 2001

E. PROPRIETARY (TRADE) NAME: **UNI-CLIP® STAPLE**

F. COMMON NAME: Bone fixation staple
True compression, adjustable and controlled.

G. CLASSIFICATION NAME AND REFERENCE:
Staple, Fixation, Bone (21 CFR, Section 888.3040)

New identification number assigned

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87JDR

J. PANEL CODE: OR

K. DESCRIPTION OF DEVICE: The **UNI-CLIP® STAPLE** is designed so that, by widening the "diamond", mechanical deformation leads to narrowing of the interaxis of the two legs. The surgeon can obtain a true compression, adjustable and controlled, with many choices of size.

L. INTENDED USE: The **UNI-CLIP® STAPLE** is implanted for fixation of bone fractures or for bone reconstructions.

M. INDICATIONS FOR USE: The **"new" UNI-CLIP® STAPLE** is indicated for fixation of bone fractures or for bone reconstruction, ~~Examples~~ include :

- Arthrodesis in hand or foot surgery
- Mono or Bi-cortical osteotomies in the foot or hand
- Fractures management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)

N. PREDICATE DEVICE: The "new" **UNI-CLIP® STAPLE** is substantially equivalent to the **UNI-CLIP® STAPLE** (K991482), the Memory Staple(DePuy) (K964226), the memograph Staple (Biomedical Ent) (K993714), the EIS Dynamic Memory Staple (Groupe Lepine) (K991962), the HTO Compression staple (Howmedica) (K895117), or the Richards Fixation Staples (Smith and Nephew Richards).

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **UNI-CLIP® STAPLE** have the same intended of use and all are indicated for fixing small fractures or osteotomies. All are made from stainless steel.

P. SUMMARY OF STUDIES: Torque of divergence and strength of compression of the Rupture torque of the "new" **UNI-CLIP® STAPLE** is the same as for the device currently cleared andfound to have a resistance to torsion in compliance with the selected standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

NewDeal SA
c/o Norman F. Estrin, Ph.D.
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K011716
Trade Name: Uni-Clip® Staple
Regulation Number: 888.3030
Regulatory Class: II
Product Code: JDR
Dated: May 30, 2001
Received: June 4, 2001

Dear Dr. Estrin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011716

Device Name: Uni-Clip Staple

Indications For Use:

The "new" uni-clip® staple is indicated for fixation of bone fracture or for bone reconstraucion, including:

- Arthrodesis in hand or foot surgery
- Mono or Bi-cortical osteotomies in the foot or hand
- Fracture management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011716

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)